

April 3, 1999

William K. Hubbard
Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

9040 '99 APR 20 P2:30

**Re: Federal Register Request for Information: Performance Standard for *Vibrio vulnificus*
Docket Number 98P-0504 -- Volume 64, Number 13, Page 3300-3301**

Dear Mr. Hubbard,

The FDA has requested information on eight points of interest in regards to issues raised by a petition submitted by Center for Science in the Public Interest. The comments here will not address these eight points directly, although conclusions may be drawn through inference.

Public health policies should not be unilaterally developed by a federal agency based upon the demands of a single special interest group (i.e. CSPI). Rather, public health policy should be developed using the best available science within the framework of a collaborative forum. Policy and regulations developed in this manner best assure industry compliance which in turn best assures public health. This is the purpose of the Interstate Shellfish Sanitation Conference which is the appropriate mechanism for dealing with the issues brought forward by CSPI.

In 1998, regulators and the shellfish industry came together effectively at the ISSC to develop an Interim Control Plan for *V. parahaemolyticus* that set far stricter control measures for the industry than what is currently required. The control plan appears to have been effective on the West Coast: illnesses associated with *V. parahaemolyticus* virtually ceased when the industry voluntarily halted sales of oysters for raw consumption, as called for in the plan.

The control plan calls not only for stricter criteria on the part of the industry, it also calls for data collection and further research so that a sound scientific basis can be developed for formulating policy. It should be incumbent on FDA to promote and develop this research, rather than eliminating consumer choice. In the Federal Register request for information, the question is asked "do data exist that would permit the setting of a performance standard," and the answer is a resounding NO. The science for setting such standards does not currently exist. Not enough is known about strains of *V. parahaemolyticus* nor what constitutes an infectious dose.

I urge the FDA to refer this matter over to the ISSC for continued deliberation and at the same time provide the funding and research necessary to develop appropriate criteria for crafting public health policy.

Sincerely,

Robert J. Lewis

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Yes! It is very
important for this
matter to be referred.

98P-0504

C99



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